



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,185	12/31/2003	Sue K. DeNise	MMI1100-2	5843

28213 7590 12/12/2007  
DLA PIPER US LLP  
4365 EXECUTIVE DRIVE  
SUITE 1100  
SAN DIEGO, CA 92121-2133

EXAMINER
----------

BAUGHMAN, MOLLY E

ART UNIT	PAPER NUMBER
----------	--------------

1637

MAIL DATE	DELIVERY MODE
-----------	---------------

12/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/750,185	<b>Applicant(s)</b> DENISE ET AL.	
	<b>Examiner</b> Molly E. Baughman	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 24,25 and 33-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-45 and 33-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendments to claims 24-25, and addition of claims 33-51, in the reply filed on 8/27/07, are acknowledged.
2. Applicant's arguments filed 8/27/07, with respect to rejection(s) of claims 24-25 under 35 USC § 112, second paragraph, have been fully considered and are persuasive in view of the amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection are made under 35 USC § 112, second paragraph, necessitated by amendment.
3. Applicant's arguments filed 8/27/07, with respect to rejection(s) of claims 24-25 under 35 USC § 112, first paragraph, written description, have been fully considered, but they are not persuasive for reasons explained in detail below. Furthermore, upon further consideration, new grounds of rejection are made under 35 USC § 112, first paragraph, written description, necessitated by amendment.
4. Applicant's arguments filed 8/27/07, with respect to rejection(s) of claims 24-25 under 35 USC § 112, first paragraph, enablement, have been fully considered, but they are not persuasive for reasons explained in detail below.
5. Claims 24-25, and 33-51 are currently under examination.

### **Claim Rejections - 35 USC § 112**

#### **35 USC § 112, second paragraph**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 24-25, and 33-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 24-25 and 33-51 are confusing because it cannot be determined what is encompassed by, "an extension primer which binds to the first and second strand of the target sequence..." in claim 24. It is unclear how a primer can bind to both strands of the target sequence.

b. Claim 24-25 and 33-51 are confusing because it cannot be determined what is encompassed by, "corresponds to" in claim 24. The scope of the term is unclear. For example, it is unclear whether the SNP is residue 300 within the sequence of SEQ ID NO:20614, or if it is residue 300 of SEQ ID NO:20614, but can comprise other sequences outside of SEQ ID NO:20614 directly adjacent, etc. It is suggested that the applicants rephrase the characterization of the SNP without using the term, "corresponding to."

c. Claim 24-25 and 33-51 are confusing because it cannot be determined what is encompassed by, "wherein each primer comprises at least 20 contiguous nucleotides which are at least 90% identical to the sequences upstream and adjacent to the SNP position" in claim 24. It is unclear what the primers are 90% identical to. For example, eliminating "which are at least 90% identical to the" from the phrase, the phrase reads, "wherein each primer comprises at least 20 contiguous nucleotides upstream and adjacent to the SNP position." Such

primers could be of any sequence, as "upstream and adjacent to the SNP position," very broadly defines any sequence, not confined to SEQ ID NO:20614. As such, it cannot be determined what is 90% identical to such sequences. Furthermore, as noted above regarding the indefiniteness of the SNP in relation to "corresponds to," this indefiniteness also causes such primer sequences to be of any sequence, not in relation to the SNP at residue 300 of SEQ ID NO:20614, nor in relation to any SNP within the bovine genome. Therefore, this further causes the phrase to be confusing.

d. Claim 24-25 and 33-51 are confusing because it is unclear what claim 24 requires for a combination. For instance, in summary, the claim is drawn to: (a), a first and second primer; or (b) complements of the first and second primers; and (c) an extension primer. The combination could be interpreted as (1) A + C; (2) B + C; (3) A or (B + C). Clarification is required.

e. Claim 24-25 and 33-51 are confusing because it cannot be determined what is encompassed by, "an extension primer which binds to the first and second strand of the target sequence downstream from the primers of (a) or (b), wherein the extension primer is a substrate for polynucleotide synthesis across the SNP position" in claim 24. First, as noted to the indefiniteness of the primers of (a) and (b), and the indefiniteness of the SNP position, it is unclear where the extension primer would therefore bind. Second, "downstream," is very broad, and does not require the primer to bind to any sequence nearby primers (a) or (b), let alone bind to anywhere on SEQ ID NO:20614. Primers as substrates for

polynucleotide synthesis across a SNP position, does not necessarily require the primer to be within a certain distance to the SNP position, and can bind anywhere within a genome that will eventually promote synthesis across a SNP position. As such, the extension primer can literally bind to anywhere on the bovine genome, or anywhere outside the bovine genome.

f. Claim 24-25 and 33-51 are confusing because it cannot be determined what is encompassed by, "wherein the first or second primer comprises a residue which is complementary to a specific sequence variant which comprises the SNP position" in claim 24. The phrase is very wordy and is therefore unclear. For instance, the phrase "a specific sequence variant which comprises the SNP position," could be interpreted as a stretch of variant nucleotides which comprise a SNP, and therefore it is unclear how the primers comprise a residue complementary thereto (i.e. Do the primers comprise one of the variant nucleotides, not complementary to the SNP position. Or, how long is this stretch of variant nucleotides, and how many possibilities are there the residue that one of the primers comprise?). Since the specification is drawn to a SNP at position 300 of SEQ ID NO:20614, being either a "g" or an "a," as represented in the original restriction requirement, it is suggested that applicants amend the claim directed to this limitation in order to further prosecution.

g. Claims 34-35 are confusing because it cannot be determined what is encompassed by, "is associated with a value of at least 50<sup>th</sup> [99<sup>th</sup>] percentile of the bovine population for the trait." It is unclear what this means, for example,

what value is the SNP associated with for at least 50<sup>th</sup> or 99<sup>th</sup> percentile of the bovine population for the trait. Clarification is required.

h. Claim 45 is confusing because it is unclear how the extension primer comprises at least 20 contiguous nucleotides which are at least 90% identical to the sequences *upstream* and *adjacent* to the SNP position when claim 24 requires the extension primer to bind *downstream* of the first and second primers, wherein one of these primers comprises a sequence that is complementary to the SNP. Clarification is required.

**35 USC § 112, first paragraph – Written Description**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 24-25 and 33-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims 24-25 and 33-51 encompass a combination of isolated polynucleotides comprising: a) a first and second primer each of which binds to a first strand of a target sequence on bovine genomic DNA, wherein the DNA comprises a

SNP position associated with a bovine trait, and wherein each primer comprises at least 20 contiguous nucleotides which are at least 90% identical to the sequences upstream and adjacent to the SNP position, where, in the first or second primer comprises a residue which is complementary to a specific sequence variant which comprises the SNP position; or b) complements of the first and second primers; and c) an extension primer which binds to the first and second strand of the target sequence downstream from the primers of (a) or (b), wherein the extension primer is a substrate for polynucleotide synthesis across the SNP position, and wherein the SNP position corresponds to nucleic acid residue 300 of SEQ ID NO:20614.

As explained in more detail in the rejections under 35 U.S.C. 112, second paragraph, the sequences encompass sequences that are at least 90% identical to any sequence, and a sequence which binds downstream therefrom, which can be any sequence at any location, not necessarily on the bovine genome. The combination thus results in an enormous number of sequence possibilities in the scope of the claim.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been disclosed. The instant specification teaches SEQ ID NO: 20614. Table 1A in the specification identifies one extension primer, particularly, SEQ ID NO: 23124, for the SNP of SEQ ID NO: 20614, and also identifies "nearby sequences:" SEQ ID NO: 47085-47105. However, due to the indefiniteness of the claims, the specification does not find support for any other sequences which fall outside of the scope of those within SEQ ID NO:20614, or its identified extension primer, SEQ ID NO:23124. It is unclear where



such noted "nearby sequences" are located in relation to SEQ ID NO:20614, since this sequence is within a contig which is not defined for its position within the bovine genome. It is unclear where such "nearby sequences" are positioned within the bovine genome as well.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other nucleotide sequences or positions within a specific gene or nucleic acid), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case the specification provides the structural limitation of a SNP at position 300 of each SEQ ID: 19473 to 21982, but such SNPs are by no means connected to each other in design, operation and effect and there is no common structure between any of the polymorphisms. The claims encompass any nucleic acid molecule that has at least 90% sequence identity to any sequence, not necessarily limited to SEQ ID NO:20614, or the bovine genome. This is an enormous genus of nucleotide, because the specification does not teach homologous sequences, or identical sequences other than SEQ ID NO: 20614 in the sequence listing.

In the instant application, the provided information does not constitute an adequate written description of the broad subject matter of the claims, and so one of skill in the art cannot envision the detailed chemical structure of an isolated polynucleotide. Adequate written description requires more than a statement that nucleic acids with a particular quality are part of the invention and reference to a potential method for their identification. The nucleic acid sequence is required.

In conclusion, the limited information provided is not deemed sufficient to reasonably convey to one skilled in the art nucleic acid molecules claimed.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

**Response to Arguments**

10. Applicant's arguments have been fully considered but they are not persuasive. Applicants argued that the claims no longer recite a polynucleotide that is at least 20 nucleotides in length and at least 90% identical to a fragment of at least 20 contiguous nucleotide of the bovine genome and that the amended claim language, "comprises at least 20 contiguous nucleotides which are at least 90% identical to the sequences upstream and adjacent to the SNP position," now provides a limited number of possibilities for variation within the sequences, particularly variations of only 2 bases. While this would be persuasive if the claim was only limited to sequences within SEQ ID NO:20614 and the SNP at position 300 thereof, the claims are replete with indefiniteness issues which cause the claims to encompass other sequences than SEQ ID NO:20614. As such, the specification still lacks support for such sequences, and any sequence which is at least 90% identical thereto.

11. Claims 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims 37-39 encompass the combination of isolated polynucleotides of claim 36, wherein the SNP is in linkage disequilibrium with one or more markers for the same trait within a distance of about 500,000 nucleotides (or 100,000 nucleotides, claim 38; or 10,000 nucleotides, claim 39) on either side of nucleic acid residue 300 of SEQ ID NO: 20614.

The claims thus encompass *any marker* within a distance of about 500,000 nucleotides for the same trait. The position of SEQ ID NO:20614 in the bovine genome, or in relation to any other SEQ ID, or contig noted in the specification is not defined, and therefore, represents an indefinite number of possibilities for markers within the bovine genome, or within any sequence (outside the bovine genome) which comprises SEQ ID NO:20614.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been disclosed. The instant specification teaches SEQ ID NO: 20614. Tables 1A and 1B identify SEQ ID NO: 20614 to be sequences 742-1341 of contig 19866881037958, however, no where in the specification does it define where this contig is located in position to any other contig or within the bovine genome. There is no description or drawing (map) which shows the layout of the contigs in relation to one other within the bovine genome. Therefore, it is unclear how one can even determine whether there are any other markers also associated with tenderness that would be in linkage disequilibrium with the

instant SNP. Furthermore, Table 1B lists other contigs which are nearby to contig 19866881037958, however, none of these contigs are listed elsewhere in the table, which would provide evidence for a SNP or marker within each nearby contig and its associated traits. Additionally, other SNPs shown to be associated with tenderness in Tables 1A, and 1B, such as MMBT02858, MMBT16580, MMBT21179, MMBT05003, MMBT18802, MMBT18799, and MMBT18797, are not a "nearby sequence" to the instant SNP, MMBT07944.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. other nucleotide sequences or positions within a specific gene or nucleic acid), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case the specification provides examples for linkage disequilibrium of other SNPs. These examples provide data for various SNP's chromosome location, base pair location, and difference in nucleotides from a particular SNP, although, none of the examples provide data for the instant SNP to be in linkage disequilibrium with any other SNP or marker.

In the instant application, the provided information does not constitute an adequate written description of the broad subject matter of the claims, and so one of skill in the art cannot envision which markers, if any, would be in linkage disequilibrium with the particular SNP at nucleotide 300 of SEQ ID NO:20614. Adequate written description requires more than a statement that the SNPs of the invention are associated with other SNPs within 500,000 nucleotides that are associated with the

same trait. A more detailed description of each SNP, comprising its location within the bovine genome, its position relating to other SNPs, and a listing of the specific SNPs in linkage disequilibrium with a particular SNP is required.

In conclusion, the limited information provided is not deemed sufficient to reasonably convey to one skilled in the art that the SNP is in linkage disequilibrium as claimed.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

**35 USC § 112, first paragraph – Enablement**

12. Claims 24-25 and 33-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention

The claims are drawn to one polymorphism at position 300 of SEQ ID NO: 20614, wherein such a polymorphism associated with the trait of bovine meat tenderness (Tables 1A and 1B). The invention is in the class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

As explained in more detail in the rejections under 35 U.S.C. 112, second paragraph, the sequences encompass sequences that are at least 90% identical to any sequence, and a sequence which binds downstream therefrom, which can be any sequence at any location, not necessarily on the bovine genome. The combination thus results in an enormous number of sequence possibilities in the scope of the claim.

Quantity of Experimentation

The quantity of experimentation in this area is very large since there is significant variability in the effects of polymorphisms on phenotypes such as bovine meat tenderness. Screening each possible polymorphism in the bovine genome represents an inventive, unpredictable and difficult undertaking in itself. This would require years of

inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is replete with evidence that gene association studies are typically wrong. In fact, Lucentini et al (The Scientist (2004) Vol 18) titled his article "Gene Association Studies Typically Wrong" and states "Two recent studies found that typically, when a finding is first published linking a given gene with a complex disease, there is only roughly a one-third chance that studies will reliably confirm the finding (see page 2 of printout)." This is consistent with the teaching of Wacholder et al (J. Natl. Cancer Institute (2004) 96(6):434-442) who notes that "Too many reports of associations between genetic variants and common cancer sites and other complex diseases are false positives (see abstract). Ioannidis (Nature genetics (2001) 29:306-309) further supports this conclusion in pointing out the heterogeneity of results among different studies of genetic polymorphisms (see abstract, for example).

Even the art associated with identifying bovine SNP markers for trait characterization, demonstrates the unpredictability of polymorphism association. Heaton et al. ("Selection and use of SNP markers for animal identification and paternity analysis in U.S. beef cattle," Mammalian Genome, 2002, Vol.13, pp.272-281) state that SNP markers and can be used for association mapping to identify chromosomal regions containing loci involved with phenotypic traits and has been advocated as a method for

mapping, however, a significant problem is the potential for spurious associations (i.e. false positives) that arise from unrecognized population stratification or recent admixture (page 279, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph). Heaton also states that at least 34 SNPs would be required to identify all 270,000 cattle registered by the American Angus Association, 40 SNPs for all of the 100 million cattle in the U.S., and 43 SNPs would be required for all of the 10 million cattle ever registered by the American Angus Association.

Therefore, it is highly unpredictable whether some currently unknown polymorphism in the bovine genome would have any association with any phenotype. Furthermore, one SNP cannot be used solely to identify a particular phenotype or genotype.

#### Working Examples

The specification has working examples where in Example 2, it explains that the SNP markers identified reach a threshold test statistic of 46.96294 for the trait of tenderness and 21.66599 ( $P < .01$ ) for the remaining four traits of retail yield, daily gain, fat thickness, and marbling were identified as associated SNPs and are listed in Tables 1A and 1B. There are no examples of any other sequences other than those in Tables 1A and 1B, which are shown to be associated with a trait.



Guidance in the Specification.

The specification does not provide sufficient evidence to demonstrate the association of any polymorphism being associated with a particular trait, nor does it provide any significant linkage equilibrium data for the polymorphisms for mapping. The specification shows a total of 2,510 polymorphisms associated with one or more traits, however it does not provide any statistical data which shows their significance to such traits, or to each other for mapping. The specification provides no reference to where any of the sequences correspond to the bovine genome in order to determine the distance and position of each sequence and how each SNP are positioned to each other. The sequences are related to particular "contigs" wherein the specification does not indicate where in the bovine genome such contigs are located and where they are located in respect to each other, and the particular SNPs listed in Tables 1A and 1B. The specification states that all the SNPs listed in Tables 1A and 1B, including the instant SNP (MMBT07944, position 300 of SEQ ID NO:20614), are associated with the respective trait(s) with a confidence level of 0.01, or higher confidence. However, the specification does not provide any description of the sequences as claimed, in relation to any SNPs, let alone the instant SNP and its association to tenderness. Since the claims are replete with indefiniteness issues which cause the claims to encompass other sequences than SEQ ID NO:20614, the claims do not encompass sequences which are shown to be associated with a particular trait.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the level of unpredictability and the teaching gene association studies are highly unpredictable is demonstrated by Heaton, Lucentini, Wacholder and Ioannidis. The specification provides one with no written description or guidance that leads one to a reliable method where any sequence as claimed is shown to be associated with a particular trait. One of skill in the art cannot readily anticipate the effect of a change within the subject matter to which the claimed invention pertains. Further the specification does not provide guidance to overcome art and specification recognized problems in the use of polymorphisms for phenotype identification and trait mapping as broadly claimed. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of working examples which do not address the full scope of the claims at issue and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

**Response to Arguments**

13. Applicant's arguments have been fully considered but they are not persuasive. While the applicants provide arguments based on enablement of the SNP located at

position 300 of SEQ ID NO:20614, the claims as amended are now replete with indefiniteness issues which cause the claims to encompass other sequences than SEQ ID NO:20614. As such, the scope of the claims are not enabled to be associated with any trait, let alone tenderness, as in the SNP at position 300 of SEQ ID NO:20614.

It is also noted that in the event the claims are amended to clarify the indefiniteness of the claims, wherein the claims are drawn to sequences within the scope of position 300 of SEQ ID NO: 20614, a scope of enablement would also apply over claims 24-25, 33-35, and 37-51, as the specification only provides support for this particular SNP (i.e. position 300 of SEQ ID NO:20614) to be associated with tenderness. It is advised that the applicants also amend the claims to limit the trait to tenderness in order to advance prosecution.

### ***Summary***

14. No claims are in condition for allowance.

### ***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is 571-272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/750,185  
Art Unit: 1637

Page 20

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Molly E Baughman  
Examiner  
Art Unit 1637

12/10/07

gnc8

\*\*\*

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

12/10/07